

## REMARKS

Subsequent to this amendment, claims 1-17 and 19-26 constitute the pending claims in this application. Claim 18 has been canceled without prejudice. Claims 14, 15, and 17 have been amended to recite methods instead of uses. Claims 22-26 have been added. Claims 22 and 24 are fully supported by original claim 17 and the specification, while claims 23 and 25-16 are fully supported by original claim 18 and the specification. No new matter has been introduced by the claim amendments. Applicants respectfully request that new claims 22-26 be grouped into Group IV.

In response to the outstanding Restriction Requirement mailed June 2, 2004, in connection with the above application, Applicants hereby elect, with traverse, Group IV (claims 14, 15, 17, and 18) which is originally drawn to use of a polypeptide. Applicants traverse the restriction requirement for the reasons which follow.

Applicants note that according to MPEP §803, two criteria must be met for a proper restriction requirement:

- A. The inventions must be independent or distinct as claimed; and
- B. There must be a serious burden on the Examiner if restriction is required.

Applicants respectfully submit that in this case, the Examiner has not shown that there would be a serious burden in examining the Groups set forth in the restriction requirement. In particular, Applicants note that it appears that the search for Groups I and IV would be co-extensive. Both these groups are classified in Class 435 and a search covering the subject matter of Group IV would cover the subject matter of Group I also, particularly in view of the present amendments. Thus, Applicants respectfully submit that the inventions of Groups I and IV can be efficiently searched and examined together without placing a significant additional burden on the Examiner.

In addition, Applicants respectfully point out that claim 14 of Group IV is a linking claim for Group I. Pursuant to MPEP 809.04, "[i]f a linking claim is allowed, the examiner must thereafter examine species if the linking claim is generic thereto, or he or she must examine the

claims to the non-elected inventions that are linked to the elected invention by such allowed linking claim.” For these reasons, Applicants respectfully request that the restriction requirement, at least with respect to Groups I and IV, be withdrawn.

In response to the election requirement, Applicants elect with traverse the gene species ygbB, for search purposes only. Applicants point out that the ygbB gene is highly related to the ygbP gene. Indeed, the ygbB nucleotide sequence (SEQ ID NO: 16) is about 51% identical to the ygbP nucleotide sequence (SEQ ID NO: 27). See the sequence alignment of ygbB and ygbP enclosed herewith as **Exhibit A**. Further, both the International Search Report (enclosed herewith as **Exhibit B**) and the Australian Examiner’s Report (enclosed herewith as **Exhibit C**) indicate that ygbB and ygbP can be reasonably searched together. Therefore, Applicants respectfully request that ygbB and ygbP be searched simultaneously.

In addition, Applicants submit that the various sequences subject to election requirement are encompassed by a Markush group. Pursuant to MPEP 803.02, “[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions.” In addition, Applicants respectfully point out that the search of the Markush-type claim will be extended to non-elected species should no prior art be found that anticipates or renders obvious the elected species (MPEP 803.02). In this case, it is Applicant’s position that the members of the Markush group are “sufficiently few in number” and may be searched and examined without a serious burden on the office.

Furthermore, Applicants note that MPEP § 803.04 states that “to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 C.F.R. 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application.” The MPEP goes on to state that “it has been determined that normally ten sequences constitute a reasonable number for examination purposes.”

Accordingly, Applicants respectfully request reconsideration and withdrawal of the election requirement, at least with respect to ygbB and ygbP, be withdrawn.

The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Date: June 30, 2004

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Respectfully Submitted,



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Tuesday, June 22, 2004 2:08 PM

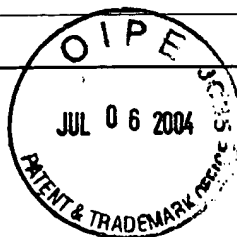
## Percent Identity

Divergence

	1	2	
1		50.9	1
2	83.1		2
	1	2	

ygbP

ygbB



ATGGGGAATTGCTCATTTGGATGTTTGGCGCCGTGGTTTTCGCTCCGTATT Majority

10 20 30 40 50

1 ATGGCAACCACCTCATTTGGATGTTTGGCGCCGTGGTTCCGGCGGCGCGATT ygbP  
1 ATGCGAATTG - - - - - GACACGGTTTGTGACGTACCAT - - ygbB

TGGCCTTTGGCTGTGAAGGGAATGTCCTAAGCAATATCTCTCAATTGTTA Majority

60 70 80 90 100

51 TGGCCGTCTGGAATGCAAAACGGGAATGTCCTAAGCAATATCTCTCAATCGGTTA ygbP  
31 - - G C C T T T G G C G G T G A A G G - - - - - C C C A A T T A T C A ygbB

TTGGTGGCGTTCTTGTTCTCTCGGTGCATGGGTTTGCTGGCGCATTTCTGGT Majority

110 120 130 140 150

101 ATCAAACCATTTCTTGAAACACTTCGGTGCATGCGCTTGCTGGCGCATTCCTCCGG ygbP  
59 TTGGTGGCGTACGCAATTCCTTACGAAAAGGAATTGCTGGCGCATTTCTGAT ygbB

GTGCGACGTGTCTGTCATTGCCATAAGTCTTGC GTTGGCCGTTTTCATTT Majority

160 170 180 190 200

151 GTGAAACGTGTCTGTCATTGCCATAAGTCTTGGCGATATAGCCGTTTTCGACACA ygbP  
109 G - G C G A C G T G G C G C - - - - - T C C A T G C G T T G A C C G A T - - G C A T T ygbB

GCTTGGTGTGGCGGCTCATCCGCAAAATCACCGTTGTGGATGTCTGGTGTATG Majority

210 220 230 240 250

201 ACTTCTCTGGCGAATCATCCGCAAAATCACCGTTGTAGATGGCGGTGTATG ygbP  
144 GCTTGGCGCGGGCGGC - - - - - TGGGGGATATCGGCGAAGC ygbB

TGTTTGGCGGATTCCGTTCTGGCATTTCTGGGTGCGCCTGGCGGCGCGCTG Majority

260 270 280 290 300

251 AGCGTGCCGATTCCGTGCTGGCAGGTCTGAAAGCCGCTGGCGACGCGCGACAG ygbP  
179 TGTTCCTCGGATAACGATCTCGGCATTTAAAAGGTGCCGATAGCCGCGCGAGCTG ygbB

TGGGTATTGGTGCATGACGCCGCTCGTCTTGTTTGCATCAGGATGACCT Majority

310 320 330 340 350

301 TGGGTATTGGTGCATGACGCCGCTCGTCTTGTTTGCATCAGGATGACCT ygbP  
229 C - - - - - ygbB

TGCGCGATTGTTGGCGTTGAGCGTATTCAGGCGCAGGGTTGTGCTCTTGG Majority

360 370 380 390 400

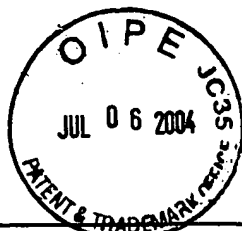
351 CGCGCGATTGTTGGCGTTGAGCGAAACACAGCCGCAACGGGGGGGATCCTCTCG ygbP  
230 TACGCGAAGCCTGGCGT - - - - - CGTATTCAGGCGAAGGGTTATATCCCTTGG ygbB

CCGCGTGGTGTGCGATACTATGATCGGTGCGGCACCGGGCAAGATGTT Majority

410 420 430 440 450

401 CCGCACCAAGTGC GCGATACTATGA AACGTGCGAGAACCGGGGCAAAATATGCC ygbP  
276 CAACGTCGATGT - - - - - CACTATCATCGCTCAAGGCACCG - - - - - AAGATGTT ygbB





International Application No. PCT/EP 00 03135

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using ygbB or ygbP

2. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using yfhC

3. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using yacE

4. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using ychB

5. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using yejD

6. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using yrfI

7. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using yggJ

8. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using yjeE

9. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using yiaO

10. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using yrdC

11. Claims: 1-21 (partially)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Method for identifying antimicrobial agents using yhbC

12. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using ybeY

13. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using gcpE

14. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using kdtB

15. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using pfs

16. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using ycaJ

17. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using b1808

18. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using yeaA

19. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using yagF

20. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using b1983

21. Claims: 1-21 (partially)

Method for identifying antimicrobial agents using yidD

22. Claims: 1-21 (partially)



FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Method for identifying antimicrobial agents using yceG

23. ✓ Claims: 1-21 (partially)

Method for identifying antimicrobial agents using yjbc

# INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No

PCT/EP 00/03135

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9842875 A	01-10-1998	US 5858367 A AU 6589098 A EP 0975801 A	12-01-1999 20-10-1998 02-02-2000
WO 9947553 A	23-09-1999	AU 2947399 A	11-10-1999
WO 9509925 A	13-04-1995	AU 686231 B AU 7702394 A EP 0722505 A HU 73691 A JP 9503131 T NZ 273643 A	05-02-1998 01-05-1995 24-07-1996 30-09-1996 31-03-1997 19-12-1997
WO 9635804 A	14-11-1996	NONE	
WO 9835054 A	13-08-1998	AU 6155398 A US 5998159 A	26-08-1998 07-12-1999
WO 9914311 A	25-03-1999	EP 1023434 A	02-08-2000

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25 September 2003

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Your Ref: 3354AUP00 CAM/jfm *33540aup00*

Examiner's report no. 2 on patent application no. 41167/00  
by GPC BIOTECH AG

Last proposed amendment no. 2

Dear Madam/Sir,

Thank you for the reply of 04.09.2003 to the last report. My report is based on the specification as if amended by the statement of proposed amendments filed with that reply and dated the same. I have considered it and believe that there are lawful grounds of objection to the application as proposed to be amended. These grounds of objection are:

6. NOTE: There is a current postponement of acceptance in place. If you overcome all other objections before the expiration of that postponement, the Commissioner will only accept the application at that time if you have filed a clear and unambiguous statement requesting the withdrawal of that postponement. Otherwise, a further adverse report will be issued.
7. The examiner maintains objection 3 of the previous report in that the present set of claims relate to multiple inventions.

The specification does not comply with Section 40(4). The claims do not relate to one invention only (or to a group of inventions so linked as to form a single general inventive concept). In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to be "special technical features". These are features that potentially distinguish the claimed combination of features from the prior art. Where different claims have different special technical features they define different inventions. I have found claims having different special technical features as follows:

- (1) Invention 1: Claims 1-21 insofar as the subject matter relates to method of identifying antibacterial agents using ygbB or ygbP. It is considered that these agents comprise a first special technical feature.

- (2) Inventions 2-23: Claims 1-21 insofar as the subject matter relates to method of identifying antibacterial agents using yfhC, etc. It is considered that these agents comprise a second special technical feature.

Since these groups of claims do not share any of the special technical features identified, a technical relationship between the inventions does not exist. Accordingly the claims do not relate to one invention or to a single inventive concept, a priori.

The issue of claims related to a method as distinguished from a sequence claim is not relevant to the present case. Unity is established if the claims share a special technical feature. I have limited the search and report to the invention defined by Inventions 1, 4, 22 and 23 as noted in the previous report. When I receive a response to my objections I may extend the search area and expand the report on the basis of my findings.

8. The examiner maintains the objection that claims 8 and 11 are not fairly based.

Claim 8 recites an antagonist or inhibitor of the activity of the polypeptide encoded by the selection of genes.

However, the antagonist or inhibitor of the claim is not limited to new compounds. The compounds include known compounds having the desired characteristic.

Further the claims cover all products having the desired characteristic or property while the specification does not provide support for such a broad claim.

The applicant submits that subject matter of the claim is limited to any antagonist or inhibitor of the activity of the polypeptide. However, the antagonist or inhibitor is not necessarily limited to any new product as a result of the present invention.

The claims to the antagonist or inhibitor should be limited to those disclosed in the present invention.

Therefore claims 8 and 11 are not fairly based.

NOTE: In the light of the above objection the examiner reserves opinion on substantive issues in regard novelty and inventive step in respect of claims 8 and 11, as noted in the previous report.

9. Claims 1-35 are not fairly based.

The terms "fragment, derivative or ortholog thereof" are too broad and not supported by the disclosure in the specification.

The skilled addressee would not readily determine which fragments, derivatives and orthologs fall within the scope of the claims.

Therefore claims 1-35 are not fairly based.

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10. The examiner maintains the objection that the invention as defined in claims 2 and 3 is not novel in the light of D1, D2 and D3.

Claim 2 recites a method of testing candidate antagonists or inhibitors of cell growth or survival by determining whether cell death or inhibition of cell growth occurs on contacting bacterial cells with one or more candidate substances. The claim specifies that the target for inhibition should be the polypeptide or mRNA of one of the essential genes *ygbB*, etc. However, the site or target for inhibition appears to be irrelevant to the outcome of the method inasmuch as an overall effect on cell growth is measured.

The method defined in the claims is standard in the art for methods used to determine antibacterial activity of candidate substances, (see D1, p50). Similarly, D2 and D3 (see claims) disclose and teach testing of antibacterial compounds as defined in claims 2 and 3 of the patent in suit.

Therefore the invention as defined in claims 2 and 3 is not novel.

You have until 5 November 2004 to overcome all my objection(s) otherwise your application will lapse. You will need to pay a monthly fee for any response you file after 12 months from the date of the first report.

Yours faithfully,



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